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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,192	08/02/2001	David C. Turner	VTN-548	6090
7590 07/21/2004			EXAMINER	
PHILIP S. JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PURVIS, SUE A	
			ART UNIT	PAPER NUMBER
			1734	

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/921,192

Applicant(s)

TURNER ET AL.

Examiner

Sue A. Purvis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,27-30 and 42-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,12-21,23-25,27-36,38-40 and 42-87 is/are rejected.
- 7) ☒ Claim(s) 11,22,26,37 and 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/2/2001, 3/4/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims 1-11, 14-26, 31-41, and 52-87 in the reply filed on 22 April 2004 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant includes "Brookfield" in the claim, but there is no mention of "Brookfield" in the specification.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Enns et al. (US Patent No. 5,779,943).

Enns discloses a method for manufacturing an article, such as a contact lens, where a normally hydrophobic/latent-hydrophilic polymerizable material is applied to the inner surfaces of a mold for making the article of manufacture; the coated mold is then filled with a monomeric material, such as silicone monomer; curing the mold contents to produce a coated article of manufacture; and treating the coated molded article to mild reaction conditions to convert the coating to a more hydrophilic form. (Col. 2, lines 57-67; Col. 3, lines 1-5.)

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 6, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art in view of Suzuki (US Patent No. 6,486,262 B1).

On pages 1 and 2 of the specification, the applicant admits that the use of hydrogels to form contact lenses is well known. That it is desirable to increase the surface wettability of hydrogel articles by coating the articles with a hydrophilic coating. Numerous hydrophilic coatings and methods for their application are known. It is known to use solution- or solvent-based coatings to coat lenses. Application of a coating onto a mold into which a lens material is dispensed has been disclosed. This method has been successfully demonstrated

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with non-silicone hydrogel materials. It is noted by the examiner that the claim uses alternative language and the mixture creating the lens does not have to contain silicone.

The admitted prior art does not disclose a "dwell time".

Suzuki teaches that "dwell time" for molding plastic lens is 1 to 300 seconds (or 5 minutes). Suzuki goes on to discuss problems with dwell time being too long or too short and a desire to ensure that the molding conditions fall within certain ranges. (Col. 12, lines 22-49.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a dwell time in the admitted prior art of less than about 5 minutes, because Suzuki teaches that it is within the purview of the artisan to have a dwell time of less than 5 minutes.

Regarding claims 6 and 18, Suzuki teaches a dwell time between 1 and 300 seconds.

8. Claims 5, 7, 8, 14, 15, 23, 31, 32, 55-63, 67-75, and 79-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art in view of Suzuki as applied to claim 1 above, and further in view of LeBoeuf et al. (US Patent No. 6,632,887 B2).

The admitted prior art in view of Suzuki does not disclose the molecular weight of the coating material.

LeBoeuf discloses that it is important for the hydrophilic polymer to have high molecular weight. (Col. 3, lines 15-26.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a high molecular weight composition within the applicant's claimed range, because LeBoeuf discloses the importance of the coating having a high molecular weight.

Regarding claim 7, Suzuki teaches a dwell time between 1 and 300 seconds.

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Regarding claims 8 and 23, both Suzuki and LeBoeuf disclose that including solvents in the coating composition is well known and its within the purview of the artisan to include a low BP solvent and a high BP solvent.

Regarding claims 55-63, 67-75, and 79-87, ethanol and ethyl lactate are well known solvents and it is within the purview of the artisan to use them and use the appropriate ratio of the solvents.

9. Claims 9, 10, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art in view of Suzuki and LeBoeuf as applied to claims 1, 8, 15, and 23 above, and further in view of Bae et al. (US Patent No. 5,667,735).

The admitted prior art in view of Suzuki and LeBoeuf does not discuss the manner in which the material is coated onto the mold.

Bae discloses spin coating is a well known means of coating a mold when making contact lenses. (Col. 1, lines 16-20.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use coating in the admitted prior art in view of Suzuki and LeBoeuf, because Bae discloses that spin coating is a well known form of coating a mold.

Regarding claims 10 and 25, the amount of coating composition is based on the size of the mold and the amount claimed is within the purview of one having ordinary skill in the art.

10. Claims 14, 15, 17, 21, 31, 36, and 38 rejected under 35 U.S.C. 103(a) as being unpatentable over Enns as described above with respect to claim 1, and further in view of Suzuki.

Enns does not discuss dwell time.

Suzuki teaches that "dwell time" for molding plastic lens is 1 to 300 seconds (or 5 minutes). Suzuki goes on to discuss problems with dwell time being too long or too short

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and a desire to ensure that the molding conditions fall within certain ranges. (Col. 12, lines 22-49.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a dwell time in Enns be less than about 5 minutes, because Suzuki teaches that it is within the purview of the artisan to have a dwell time of less than 5 minutes for curing contact lenses.

Regarding claim 21, in claim 5 of Enns the coating composition is detailed as including methacrylic acid.

Regarding claims 31 and 36, Enns does not disclose the molecular weight of the coating composition, but does teach having a methacrylic acid in the composition as set forth in claim 36, thus its within the purview of the artisan to have the molecular weight as defined by the applicant in claim 31.

Regarding claim 38, Suzuki discloses that including solvents in the coating composition is well known and its within the purview of the artisan to include a low BP solvent and a high BP solvent.

11. Claims 19, 20, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enns as applied to claims 14, 17, 31, and 33 above, and further in view of Ford et al. (US Patent No. 6,551,531 B1).

Enns does not detail in silicone monomer mixture

Ford discloses that the standard mixture for creating ophthalmic lens. (Col. 2, lines 15-31; Col. 6, lines 48-67.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to look to know a standard mixture for creating contact lens, because Ford teaches that the forming mixture is well known.

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12. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enns in view of Suzuki as applied to claims 31, 36, and 38 above, and further in view of Bae et al.

Enns in view of Suzuki does not discuss the manner in which the material is coated onto the mold.

Bae discloses spin coating is a well known means of coating a mold when making contact lenses. (Col. 1, lines 16-20.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use coating in Enns in view of Suzuki, because Bae discloses that spin coating is a well known form of coating a mold.

Regarding claim 40, the amount of coating composition is based on the size of the mold and the amount claimed is within the purview of one having ordinary skill in the art.

13. Claims 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enns as applied to claims 1 above.

Enns discloses that viscosity of the coating composition can be manipulated. (Col. 5, lines 19-26.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to manipulate the viscosity of the coating composition based on the needs of the artisan as disclosed in Enns. Thus it is within the purview of the artisan to have the coating composition be the viscosities as claimed in the instant application.

14. Claims 64-66 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enns in view of Suzuki as applied to claims 14 and 31 above.

Enns discloses that viscosity of the coating composition can be manipulated. (Col. 5, lines 19-26.)



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It would have been obvious to one having ordinary skill in the art at the time the invention was made to manipulate the viscosity of the coating composition based on the needs of the artisan as disclosed in Enns. Thus it is within the purview of the artisan to have the coating composition be the viscosities as claimed in the instant application.

***Allowable Subject Matter***

15. Claims 11, 22, 26, 37, and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is an examiner's statement of reasons for allowance:

a. Regarding claims 11 and 26, prior art does not teach or suggest including a pressurized air jet to an edge of the mold as required by these claims.

b. Regarding claims 22, 37, and 41, there is no teaching or suggestion in Enns or the other references cited herein to have to coating composition include poly(2-hydroxyethyl methacrylate) as required by the claim.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue A. Purvis whose telephone number is (571) 272-1236. The examiner can normally be reached on Monday through Friday 9am to 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher A. Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sue A. Purvis', with a long horizontal line extending to the right.

Sue A. Purvis  
Primary Examiner  
Art Unit 1734

SP  
July 10, 2004